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| 10/564,274 | 01/10/2006 | Jung-hoon Kim | 0117.20 | 7381 |

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| EXAMINER | |
|---|---|
| MARX, IRENE | |

| ART UNIT | PAPER NUMBER |
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| 1651 | |

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| 12/24/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/564,274 | KIM ET AL. | |
| | Examiner | Art Unit | |
| | Irene Marx | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) *2-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 3and 5-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

The amendment filed 10/24/08 is acknowledged. Claims 1, 5 and 6 are being considered on the merits.

Claims 2-4 are withdrawn from consideration as directed to a non-elected invention.

The rejection under 35 U.S.C 112, first paragraph regarding deposit is withdrawn in view of applicant's averments.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the strain *Candida tropicalis* CJ-FID containing "an isolated nucleotide sequence of SEQ ID NO: 1". Even though the sequence was originally isolated from the strain, it is not apparent from the record that the isolated sequence was reinserted into the respective microorganism. Moreover, only one sequence is disclosed and not several as suggested by "an".

Therefore, this material constitutes new matter and should be deleted.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of "comprising an isolated nucleotide sequence of SEQ ID NO: 1". It is unclear that the microorganism is provided with an isolated nucleotide sequence, even when reading the claim in light of the specification. Moreover, only one sequence is disclosed and not several as suggested by "an".

See, also, the new matter rejection *supra.*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Barbosa *et al.*, Journal of Industrial Microbiology, 1988, vol. 3, pages 241-251, in light of Lima *et al.* (of record.)

The claims are drawn to a *C. tropicalis* strain which produces xylitol.

The cited reference discloses a *C. guillermondi* strain which produces xylitol which appears to be identical to the presently claimed strain (see, e.g., page 242) since it produces xylitol under substantially similar process conditions.. Lima *et al.* adequately demonstrate that this strain is properly classified as *C. tropicalis* (See, e.g., page 6)

The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it is of the same class as that of the microorganism claimed and is taught to be effective to produce the same product. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the strain of the reference cannot be compared with the instant strain because it does not have a deposit number. It is noted that there is no requirement that prior art strains be deposited for comparison purposes. Applicants can request and obtain the strain from the reference authors, for example.

On the other hand, applicant also argues that the instant strain is more productive than the strain of Barbosa *et al.* citing the specification, page 16. From the touted Table 2 it cannot be readily assessed whether or not the results pertain to a side-by-side comparison. This is of particular interest since Barbosa *et al.* strongly suggest that process conditions directly affect the yield.

Thus, Applicants have not resolved the issue of whether, in fact, the reference strain is one and the same as the claimed strains and, hence, anticipates the same, or whether the characteristics of the reference strains are so closely related to those of the claimed strain as to render same obvious to one of ordinary skill in the art. Any determination regarding identity or obviousness of microorganisms requires culturing such strains under the same conditions in a side-by-side comparison, since a comparison of the inherent properties of the reference and claimed microorganisms is probative of differences, rather than merely a comparison of the described characteristics ascertained under dissimilar conditions, which includes the production of xylitol. Since the PTO is not equipped to test microorganisms for comparative purposes, the

burden falls of applicants to ascertain whether the strains claimed are the same or different from reference strains.

Regarding the searches in the sequence data bases, the fact that a similar sequence is not disclosed therein is not dispositive of whether or not the prior art strain renders the claimed strain anticipated or obvious. Sequence data are available only for a limited number of strains within a few species.

Consequently, applicants have failed to overcome the rejection. Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651